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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/230,137 08/10/99 CUNNINGHAM

R 23861-001

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IM22/1107

EXAMINER

CROSS, L

ART UNIT	PAPER NUMBER
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1743

DATE MAILED:

11/07/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/230,137

Applicant(s)

Cunningham

Examiner

LaToya I. Cross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 27-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

This Office Action is in response to Applicants' amendment filed on August 24, 2001 and entered as Paper No. 9. Claims 1-25 and 27-31 are pending in the instant application. Claim 26 was cancelled by amendment.

Withdrawal of Rejections from Previous Office Action

The rejection of claims 8 and 19-25 under 35 USC 112, second paragraph is withdrawn in view of Applicants' amendment to clarify the claims.

The rejection of claims 19-25 under 35 USC 102b over Haswell '041 is withdrawn in view of Applicants' amendment to the claims to denote that the test kit comprises the test device inside of a suitably sized pouch.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-25 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,460,057 to Ostrup in view of US Patent 5,334,502 to Sangha.

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Applicant's claimed invention is directed to a test device comprising a substrate; an indentation/aperture in said substrate; supportive material mounted on said substrate; guide means; and sample indicating means.

Ostrup '057 discloses an apparatus for handling biological samples. The apparatus includes a sample collection unit/card (20) comprising a substrate (22) and several apertures (25) that are evenly spaced apart from one another. Absorbent filter paper (30) is disposed over each aperture. The card is provided with a mark (34) for providing the location of acceptable sample and an optimum point for punching (35). The sample collection card has a handle portion that allows an automatic apparatus to easily access the collected sample. Marks (34, 35) are used by the camera to determine the ideal location for punching out the portion of the filter paper containing the sample. Ostrup '057 also discloses an assembly for the sample collection card, shown by figure 6 and a package shown by figure 8.

Ostrup '058 does not teach a guide means having a sample deposition portion connected to a channel portion.

Sangha '502 teaches a device for collecting biological samples. The device of Sangha '502 comprises an absorbent layer (30) onto which sample is deposited. As the user deposits sample onto the center portion (32) of the absorbent layer, a one way barrier (38) leads the sample to the indicator (39) where a colored signal will denote the presence of a sufficient amount of sample. The indicator is situated on top of the one-way barrier, which allows the collected sample to move upwardly from the absorbent sheet and contact the indicator.

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It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to use such a guide means, as disclosed by Sangha '502, in the sample collection card of Ostrup '057 for the purpose of alerting the user of the presence of a sufficient amount of sample on the card. Such a modification would provide an easy manner for determining the amount of sample that has been collected, without the use of mechanical means such as a camera.

Therefore, for the reasons set forth above, Applicant's claimed invention is deemed to be obvious, within the meaning of 35 USC 103, in view of the teachings of Ostrup '057 and Sangha '502.

Response to Arguments

3. Applicant's arguments filed August 24, 2001 have been fully considered but they are not persuasive. Applicants' arguments regarding the rejection over Ostrup '057 in view of Sangha '502 are directed to 1) Ostrup uses a camera to judge the best position for punching the absorbent pad and 2) Applicants' assertion that the means for denoting the presence of a sufficient amount of sample in Sangha is not the same as Applicants' guide means.

Applicants correctly indicate that Ostrup '057 uses a camera to determine the position of the absorbent pad that contains the greatest concentration of sample. The rejection uses Sangha '502 to correct this deficiency and provide a simpler, alternative means for determining whether a sufficient amount of sample has been collected. Applicants argue that Sangha's means for signaling a sufficient amount of sample may

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give erroneous results because of the location of the indicator in relation to the location of the position where sample is deposited. Applicants are incorrect in stating that in Sangha, the indicator is in close proximity to the sample deposition portion. Sangha teaches at col. 8, lines 3-11, that the indicator is located on top of the one-way barrier. When sample is deposited onto the absorbent pad, the sample has to move upward from the absorbent sheet to contact the indicator. This upward movement can be construed as channeling action. Applicants are also incorrect in stating the Sangha's means will allow the indicator to contaminate the sample. At col. 8, lines 11-17, Sangha teaches the upward movement of the sample to contact the indicator is not reversible. Therefore, any sample that has contacted the indicator will not contaminate other sample.

It is submitted that Applicants' invention is obvious over the combination of Ostrup and Sangha. The skilled artisan would recognize the advantages of providing a sample collection card with an indicator to allow the user to know when sufficient sample has been collected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 703-305-7360. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 703-308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-5408 for regular communications and 703-305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

LIC
November 5, 2001


Jill Warden
Supervisory Patent Examiner
Technology Center 1700